



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0008]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see ADDRESSES) by **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see ADDRESSES) by **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Nominations

will be accepted for current vacancies and for those that will or may occur through December 31, 2022.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process should be submitted electronically to ACOMSSubmissions@fda.hhs.gov or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002.

Consumer representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>, or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002. Additional information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: *For questions relating to participation in the selection process:* Kimberly Hamilton, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5122, Silver Spring, MD 20993-0002, 301-796-8220, Kimberly.Hamilton@fda.hhs.gov.

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1.

Table 1.--Advisory Committee Contacts

Contact Person	Committee/Panel
Rakesh Raghuwanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4769, Rakesh.Raghuwanshi@fda.hhs.gov.	FDA Science Board Advisory Committee
Shivana Srivastava, Office of Pediatric Therapeutics Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5157, Silver Spring, MD 20993-0002, 301-796-8695, Shivana.Srivastava@fda.hhs.gov.	Pediatrics Advisory Committee
Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1226, Silver Spring, MD	Allergens Products Advisory Committee

Contact Person	Committee/Panel
20993-0002, 240-402-8006, Prabhakara.Atreya@fda.hhs.gov.	
LaToya Bonner, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2428, Silver Spring, MD 20993-0002, 301- 796-2855, LaToya.Bonner@fda.hhs.gov.	Endocrinologic and Metabolic Drugs Advisory Committee
Moon Hee Choi, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2434, Silver Spring, MD 20993-0002, 301- 796-2894, MoonHee.Choi@fda.hhs.gov.	Non-Prescription Drugs Advisory Committee
Joyce Frimpong, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2462, Silver Spring, MD 20993-0002, 301- 796-7973, Joyce.Frimpong@fda.hhs.gov.	Psychopharmacologic Drugs Advisory Committee
Candace Nalls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993-0002, 301- 636-0510, Candace.Nalls@fda.hhs.gov.	Anesthesiology and Respiratory Therapy Devices Panel, Clinical Chemistry and Clinical Toxicology Devices Panel, Gastroenterology and Urology Devices Panel, General and Plastic Surgery Devices Panel
Akinola Awojope, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5216, Silver Spring, MD 20993-0002, 301-636-0512, Akinola.Awojope@fda.hhs.gov.	Dental Products Devices Panel, Obstetrics and Gynecology Devices Panel, Orthopaedic and Rehabilitation Devices Panel
James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5211, Silver Spring, MD 20993-0002, 301- 796-6313, James.Swink@fda.hhs.gov.	Circulatory System Devices Panel, Immunology Devices Panel, Microbiology Devices Panel, Ophthalmic Devices Panel
Jarrold Collier, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1333, Silver Spring, MD 20993-0002, 240- 672-5763, Jarrod.Collier@fda.hhs.gov.	General Hospital and Personal Use Devices Panel, Hematology and Pathology Devices Panel, Molecular and Clinical Genetics Devices Panel, National Mammography Quality Assurance Advisory Committee, Radiology Devices Panel
Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993-0002, 301-796-8398, Letise.Williams@fda.hhs.gov.	Patient Engagement Advisory Committee

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2:

Table 2.--Committee Descriptions, Type of Consumer Representative Vacancy, and Approximate Date Needed

Committee/Panel/Areas of Expertise Needed	Type of Vacancy	Approximate Date Needed
FDA Science Board Advisory Committee--The Science Board provides advice to the Commissioner of Food and Drugs (Commissioner) and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda, and on upgrading its scientific and research facilities and training opportunities. It also provides, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.	1--Voting	Immediately
Pediatrics Advisory Committee--Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one representative from a	1--Voting	June 1, 2022

pediatric health organization and one representative from a relevant patient or patient-family organization and may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.		
Allergenics Products Advisory Committee--Knowledgeable in the fields of allergy, immunology, pediatrics, internal medicine, biochemistry, and related specialties.	1--Voting	Immediately
Endocrinologic and Metabolic Drugs Advisory Committee--Knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties.	1--Voting	July 1, 2022
Non-Prescription Drugs Advisory Committee--Knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties.	1--Voting	June 1, 2022
Psychopharmacologic Drugs Advisory Committee--Knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties.	1--Voting	July 1, 2022
Anesthesiology and Respiratory Therapy Devices Panel--Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	1--Nonvoting	Immediately
Clinical Chemistry and Clinical Toxicology Devices Panel--Doctor of Medicine or Philosophy with experience in clinical chemistry (e.g., cardiac markers), clinical toxicology, clinical pathology, clinical laboratory medicine, and endocrinology.	1--Nonvoting	Immediately
Gastroenterology and Urology Devices Panel--Gastroenterologists, urologists, and nephrologists.	1--Nonvoting	Immediately
General and Plastic Surgery Devices Panel--Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic, and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	1--Nonvoting	Immediately
Dental Products Devices Panel--Dentists, engineers, and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	1--Nonvoting	Immediately
Obstetrics and Gynecology Devices Panel--Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	1--Nonvoting	Immediately
Orthopaedic and Rehabilitation Devices Panel--Orthopedic surgeons (joint spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians.	1--Nonvoting	Immediately
Circulatory Systems Devices Panel--Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1--Nonvoting	Immediately
Immunology Devices Panel--Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1--Nonvoting	Immediately
Microbiology Devices Panel--Clinicians with an expertise in infectious disease, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in	1--Nonvoting	Immediately

tropical medicine and emerging infectious diseases, mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists.		
Ophthalmic Devices Panel--Ophthalmists with expertise in corneal-external disease, vitreo-retinal surgery, glaucoma, ocular immunology, ocular pathology; optometrists; vision scientists; and ophthalmic professionals with expertise in clinical trial design, quality of life assessment, electrophysiology, low vision rehabilitation, and biostatistics.	1--Nonvoting	Immediately
General Hospital and Personal Use Devices Panel--Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers, or microbiologists/infection control practitioners or experts.	1--Nonvoting	Immediately
Hematology and Pathology Devices Panel--Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and hemostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive biomarkers.	1--Nonvoting	Immediately
Molecular and Clinical Genetics Devices Panel--Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. The Agency is also interested in considering candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology, and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics, as well as ancillary fields of study will be considered.	1--Nonvoting	Immediately
Radiological Devices Panel--Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties, and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging, and image analysis.	1--Nonvoting	Immediately
National Mammography Quality Assurance Advisory Committee--Physician, practitioner, or other health professional whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography.	4--Voting	Immediately
Patient Engagement Advisory Committee--Experts who are knowledgeable in areas such as clinical research, primary care patient experience, and healthcare needs of patient groups in the United States. Selected Committee members may also be experienced in the work of patient and health professional organizations; methodologies for eliciting patient preferences; and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects.	1--Voting	Immediately

I. Functions and General Description of the Committee Duties

A. FDA Science Board Advisory Committee

The Science Board Advisory Committee (Science Board) provides advice to the Commissioner of Food and Drugs (Commissioner) and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice that

supports the Agency in keeping pace with technical and scientific developments, including in regulatory science, and input into the Agency's research agenda and on upgrading its scientific and research facilities and training opportunities. It also provides, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

B. Pediatrics Advisory Committee

The Committee advises and makes recommendations to the Commissioner regarding (1) pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics; (4) pediatric labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary of Health and Human Services (HHS) directly or to the Secretary of HHS through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

C. Allergenics Advisory Committee

Reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease as well as the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products, and on the quality and relevance of FDA's research programs.

D. Endocrinologic and Metabolic Drugs Advisory Committee

Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders.

E. Nonprescription Drugs Advisory Committee

Review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of Agency-sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

F. Psychopharmacologic Drugs Advisory Committee

The Psychopharmacologic Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human products for use in the practice of psychiatry and related fields.

G. Certain Panels of the Medical Devices Advisory Committee

The Medical Devices Advisory Committee has established certain panels to review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area: (1) advises on the classification or reclassification of devices into one of three regulatory categories and advises on any possible risks to health associated with the use of devices; (2) advises on formulation of product development protocols; (3) reviews premarket approval applications for medical devices; (4)

reviews guidelines and guidance documents; (5) recommends exemption of certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; (6) advises on the necessity to ban a device; and (7) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

H. National Mammography Quality Assurance Advisory Committee

The National Mammography Quality Assurance Advisory Committee advises the Agency on the following: development of appropriate quality standards and regulations for mammography facilities; standards and regulations for bodies accrediting mammography facilities under this program; regulations with respect to sanctions; procedures for monitoring compliance with standards; establishing a mechanism to investigate consumer complaints; and reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities. The Committee also advises the Agency on determining

whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; determining whether there exist a sufficient number of medical physicists; and determining the costs and benefits of compliance with these requirements.

I. Patient Engagement Advisory Committee

The Patient Engagement Advisory Committee advises the Agency on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee may consider topics such as Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues, and other patient-related topics. The Committee will provide relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes and increase integration of patient perspectives into the regulatory process for medical devices. The Committee will perform its duties by discussing and providing advice and recommendation in ways such as identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

II. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) demonstrate an affiliation with and/or active participation in consumer or community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see ADDRESSES) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or résumé. Ballots are to be filled out and returned to FDA within 30 days. The nominee receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

IV. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee and a signed copy of the *Acknowledgement and Consent* form available at the FDA Advisory Nomination Portal (see ADDRESSES), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations must also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research

grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms of up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-01724 Filed: 1/27/2022 8:45 am; Publication Date: 1/28/2022]